

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION

John Scaro & Joanne Scaro  
7548 Deer Path  
Brecksville, Ohio 44141

Plaintiff,

vs.

Takeda Pharmaceuticals America, Inc.  
c/o CT Corporation System  
1300 East Ninth Street  
Cleveland, Ohio 44114;

and

Takeda Pharmaceuticals North America, Inc.  
c/o CT Corporation System  
208 South LaSalle Street  
Chicago, Illinois 60604;

and

Takeda Pharmaceutical Company Limited  
c/o President Yasuchika Hasegawa  
1-1, Doshomachi 4-chome,  
Chuo-ku, Osaka 540-8645;

and

Eli Lilly and Company (99-06)  
c/o National Registered Agents, Inc.  
145 Baker Street  
Marion, Ohio 43302

Defendants.

**COMPLAINT AND DEMAND  
FOR JURY TRIAL**

## **COMPLAINT**

Plaintiff John Scaro (alternatively referred to as “Plaintiff”), residing in the City of Brecksville and County of Cuyahoga, within the State of Ohio, by and through the undersigned attorneys, hereby brings this cause of action against Defendants Takeda Pharmaceuticals America, Inc. (“Takeda America”), Takeda Pharmaceuticals North America, Inc. (“Takeda North America”) and Takeda Pharmaceutical Company Limited (“Takeda Limited”)(collectively “Takeda” or “Defendants”) and Eli Lilly and Company (“Lilly” or collectively with Takeda as “Defendants”) and as for his Complaint alleges, upon information and belief and based on the investigation to date of counsel, as follows:

## **INTRODUCTION**

1. This is a personal injury action brought for injuries caused to Plaintiff as a result of ingesting Defendants’ defective drug Actos (pioglitazone), a prescription medication used to improve blood sugar (glucose) control in adults with type II diabetes.

## **JURISDICTION AND VENUE**

2. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds \$75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in states other than the state in which the named Plaintiff resides.

3. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. § 1367.

4. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to Plaintiffs’ claims occurred, in part, in the Eastern District of Ohio.

**PLAINTIFF**

5. Plaintiff, John Scaro, is a natural person and a resident of the City of Brecksville, in the State of Ohio and used the prescription Actos as prescribed and directed by his physician.

6. Plaintiff was injured as a result of his use of Actos, and therefore seeks damages, ascertainable economic losses, attorneys' fees, reimbursement of cost of obtaining Actos, reimbursement for all past, present, and future health and medical care costs related to Actos.

**DEFENDANTS**

7. Takeda America is a Delaware Corporation which has its principal place of business at One Takeda Parkway Deerfield, IL 60015.

8. Takeda America is a wholly owned subsidiary of Takeda North America.

9. Takeda America has transacted and conducted business within the State of Ohio.

10. Takeda America has derived substantial revenue from goods and products, including Actos, used in the State of Ohio.

11. Takeda America expected or should have expected their acts to have consequences within the State of Ohio, and derived substantial revenue from interstate commerce.

12. Takeda North America is a Delaware corporation which has its principal place of business at One Takeda Parkway Deerfield, IL 60015.

13. Takeda North America is a wholly owned subsidiary of Takeda Limited.

14. Takeda North America has transacted and conducted business within the State of Ohio.

15. Takeda North America has derived substantial revenue from goods and products, including Actos, used in the State of Ohio.

16. Takeda North America expected or should have expected their acts to have consequences within the State of Ohio, and derived substantial revenue from interstate commerce.

17. Takeda Limited is a foreign corporation with its principal place of business located at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka, 540-8645, Japan.

18. Takeda Limited is the parent company of Takeda North America, and Takeda America is a wholly-owned subsidiary of Takeda North America.

19. Takeda Limited has transacted and conducted business within the State of Ohio.

20. Takeda Limited has derived substantial revenue from goods and products, including Actos, used in the State of Ohio.

21. Takeda Limited expected or should have expected their acts to have consequences within the State of Ohio, and derived substantial revenue from interstate commerce.

22. Lilly is an Indiana corporation with its principal place of business located at Lilly Corporate Center, Indianapolis, Indiana 46285.

23. Lilly has transacted and conducted business within the State of Ohio.

24. Lilly has derived substantial revenue from goods and products, including Actos, used in the State of Ohio.

25. Lilly expected or should have expected their acts to have consequences within the State of Ohio, and derived substantial revenue from interstate commerce.

#### **SUMMARY OF THE CASE**

26. As a result of the defective nature of Actos, persons who were prescribed and ingested this product, including Plaintiff, have suffered and may continue to suffer from bladder cancer.

27. Defendants concealed and continue to conceal their knowledge of Actos'

unreasonably dangerous risks from Plaintiff, his physicians, other consumers, and the medical community. Specifically, Defendants failed to adequately inform consumers and the prescribing medical community about the risk of bladder cancer associated with more than twelve (12) months of Actos ingestion.

28. As a result of Defendants' actions and inaction, Plaintiff was injured due to his ingestion of Actos, which caused and will continue to cause Plaintiff's injuries and damages. Plaintiff accordingly seeks damages associated with these injuries.

### **FACTUAL ALLEGATIONS**

29. Defendants, directly or through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed, promoted and sold Actos, for the treatment of type two diabetes mellitus.

30. Actos was jointly launched by Takeda North America and Lilly in 1999.

31. On April 20, 2006, Takeda Limited announced the conclusion of its collaboration in the United States between Takeda North America and Lilly to promote and market Actos, a partnership Takeda Limited described as "a great success" and "mutually beneficial to both companies."

32. According to the American Diabetes Association, type II diabetes is the most common form of diabetes. Type II diabetes develops when the body does not produce enough insulin or doesn't efficiently use the insulin that it does produce. Type I diabetes occurs when the body does not produce any insulin at all. Insulin is necessary for the body to be able to use glucose for energy.

33. Actos was approved by the Food and Drug Administration ("FDA") in July of 1999 to treat type II diabetes. Actos is in a class of insulin-sensitizing diabetes agents known as thiazolidinediones ("TZD"s).

34. Actos exerts its antihyperglycemic effect only in the presence of endogenous insulin. Therefore, Actos is only used to treat type II diabetes and should not be used to treat type I diabetes.

35. Actos is sold as a single ingredient product under the brand name Actos, and it is also sold in combination with metformin (Actoplus Met, Actoplus Met XR) and in combination with glimepiride (Duetact).

36. As a result of the defective nature of Actos, persons who were prescribed and ingested Actos for more than twelve (12) months, including Plaintiff, have suffered and may continue to suffer from bladder cancer.

37. Defendants concealed and continue to conceal their knowledge that Actos can cause bladder cancer from Plaintiff, other consumers, and the medical community. Specifically, Defendants have yet to adequately inform consumers and the prescribing medical community about the risks of bladder cancer with use of Actos for more than twelve (12) months.

38. As a result of Defendants' actions and inactions, Plaintiff was injured due to his ingestion of Actos, which caused and will continue to cause Plaintiff various injuries and damages. Plaintiff accordingly seeks damages associated with these injuries.

39. Prior to Actos being approved by the FDA, a two-year carcinogenicity study was conducted on male and female rats. Drug-induced tumors were observed in male rats receiving doses of Actos that produced blood drug levels equivalent to those resulting from a clinical dose.

40. In 2005, the results of the PROactive (**PRO**spective PioglitAzone **Clinical Trial In MacroVascular Events**) three-year study were published. PROactive prospectively looked at the impact in total mortality and macrovascular morbidity using Actos. Dormandy J.A., et al. *Secondary Prevention of Macrovascular Events in Patients with Type 2 Diabetes in the*

*PROactive Study (PROspective PioglitAzone Clinical Trial In MacroVascular Events): a Randomised Controlled Trial*, Lancet, 266:1279-1289 (2005).

41. The PROactive study was looking at cardiovascular events and outcomes. However, the study demonstrated a higher percentage of bladder cancer cases in patients receiving Actos versus comparators. This information was not included in the published Dormandy paper.

42. A three-year liver safety study was also performed, and according to the FDA, that study also demonstrated a higher percentage of bladder cancer cases in patients receiving Actos versus comparators.

43. On September 17, 2010, the FDA issued a Safety Announcement stating it was undertaking a review of the data from an ongoing, ten-year epidemiological study being conducted by Kaiser Permanente to evaluate the association between Actos and bladder cancer. The planned five-year interim analysis demonstrated that the risk of bladder cancer increases with increasing dose and duration of Actos use, reaching statistical significance after 24 months.

44. Despite this finding by the FDA, Robert Spanheimer, Vice President of Medical and Scientific Affairs for Takeda, claimed to Reuters that the Kaiser Permanente study has not shown a risk to patients of bladder cancer or other cancers from Actos.

45. In early 2011, the American Diabetes Association published *Assessing the Association of Pioglitazone Use and Bladder Cancer Through Drug Adverse Event Reporting*, Piccinni, et al. Diabetes Care, 34:1369-1371 (June 2011), published ahead of print April 22, 2011. This study looked at adverse events reports made to the FDA between 2004 and 2009. The conclusion of that study was that “[i]n agreement with preclinical and clinical studies, AERS

analysis is consistent with an association between pioglitazone and bladder cancer. This issue needs constant epidemiologic surveillance and urgent definition by more specific studies.”

46. On June 9, 2011, the European Medicines Agency (“EMA”) announced that it had been informed by the French Medicines Agency (“Afssaps”) of its decision to suspend the use of pioglitazone-containing medicines (Actos, Competact) in France while awaiting the outcome of the ongoing European review.

47. France’s decision was based upon a retrospective cohort study in France using the French National Health Insurance Plan which demonstrated a statistically significant increase in the risk for bladder cancer in males exposed to Actos for more than a year. The French cohort included 1.5 million patients with diabetes that were followed for 4 years (2006-2009).

48. On June 10, 2011, Reuters published that Germany had joined France in suspending the use of Actos after Germany’s Federal Institute for Drugs and Medical Devices (“BfArM”) reviewed the results of the French study. BfArM recommended that doctors should not put new patients on pioglitazone.

49. On June 15, 2011, the FDA issued another Safety Announcement stating that “use of the diabetes medication Actos (pioglitazone) for more than one year may be associated with an increased risk of bladder cancer.” The FDA ordered information about this risk to be added to the *Warnings and Precautions* section of the label for pioglitazone-containing medicines.

50. The FDA reported that the risk of bladder cancer increased with increasing dose and duration of pioglitazone use. When compared to persons never exposed to pioglitazone, exposed to pioglitazone therapy for longer than 12 months was associated with a 40% increase in risk. Based on this data, the FDA calculated that therapy with Actos for longer than 12 months

was associated with 27.5 excess cases of bladder cancer per 100,000 person-years follow-up, compared to those who never used pioglitazone.

51. On July 12, 2011, Takeda Limited issued a recall on Actos in France.

52. As the manufacturers of Actos, Defendants knew or should have known that Actos use for longer than 12 months was associated with bladder cancer. Instead, Defendants promoted Actos as a safe and effective treatment for type II diabetes.

53. Piccinni, et al. analyzed the association between antidiabetic drugs and bladder cancer by reviewing reports from the FDA Adverse Event Reporting System (“AERS”) between 2004 and 2009. The association was analyzed by the case/noncase methodology. There were 31 recorded reports of bladder cancer in patients using pioglitazone. Piccinni’s results indicated that the reporting odds ratio for pioglitazone was indicative of a “definite risk.” *Assessing the Association of Pioglitazone Use and Bladder Cancer Through Drug Adverse Event Reporting*, Piccinni, et al. *Diabetes Care*, 34:1369-1371 (June 2011), published ahead of print April 22, 2011.

54. Despite its knowledge of this dangerous side effect that can result from Actos use, Defendants refused to warn patients, physicians and the medical community about the risk of bladder cancer.

55. Actos is one of Defendants’ top selling drugs. Upon information and belief, in the last year, the medication had global sales of \$4.8 billion and accounted for approximately 27% of Takeda’s revenue. In 2008, Actos was the tenth best-selling medication in the United States.

56. Consumers, including Plaintiff, who have used Actos for treatment of type II diabetes, have several alternative safer products available to treat the conditions and have not been adequately warned about the significant risks and lack of benefits associated with long-term Actos therapy.

57. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and his physicians the true and significant risks associated with long-term Actos use.

58. As a result of Defendants' actions, Plaintiff and his prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Complaint, and that those risks were the direct and proximate result of Defendants' acts, omissions, and misrepresentations.

59. Plaintiff was prescribed and began taking Actos in 2009 upon direction of his physician. Plaintiff subsequently developed bladder cancer in February 2011.

60. As a direct result of being prescribed Actos for more than twelve months, Plaintiff has been permanently and severely injured, having suffered serious consequences from long-term Actos use. Plaintiff requires and will in the future require ongoing medical care and treatment.

61. Plaintiff, as a direct and proximate result of long-term Actos use, suffered severe mental and physical pain and suffering and has and will sustain permanent injuries and emotional distress, along with economic loss due to medical expenses, and living related expenses due to his new lifestyle.

62. Plaintiff would not have used Actos had Defendants properly disclosed the risks associated with its long-term use.

#### **FEDERAL REQUIREMENTS**

63. Defendants had an obligation to comply with the law in the manufacture, design, and sale of Actos.

64. Upon information and belief, Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, *et seq.*

65. With respect to the prescription drug Actos, the Defendants, upon information and belief, has or may have failed to comply with all federal standards applicable to the sale of prescription drugs including, but not limited to, one or more of the following violations:

- a. The prescription drug Actos is adulterated pursuant to 21 U.S.C. § 351 because, among other things, it fails to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture, packing, storage or installation is not in conformity with federal requirements. See, 21 U.S.C. § 351.
- b. The prescription drug Actos is adulterated pursuant to 21 U.S.C. § 351 because, among other things, its strength differs from or its quality or purity falls below the standard set forth in the official compendium for ACTOS and such deviations are not plainly stated on their labels.
- c. The prescription drug Actos is misbranded pursuant to 21 U.S.C. §352 because, among other things, it's labeling is false or misleading.
- d. The prescription drug Actos is misbranded pursuant to 21 U.S.C. §352 because words, statements, or other information required by or under authority of chapter 21 U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.
- e. The prescription drug Actos is misbranded pursuant to 21 U.S.C. §352 because the labeling does not bear adequate directions for use, and/or the labeling does not bear adequate warnings against use where its use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users.
- f. The prescription drug Actos is misbranded pursuant to 21 U.S.C. §352 because it's dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.
- g. The prescription drug Actos does not contain adequate directions for use pursuant to 21 CFR § 201.5, because, among other reasons, of omission, in whole or in part, or incorrect specification of (a) statements of all conditions, purposes, or uses for which it is intended, including conditions, purposes, or

uses for which it is prescribed, recommended or suggested in their oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drugs are commonly used, (b) quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions, (c) frequency of administration or application, (d) duration or administration or application, and/or (d) route or method of administration or application.

- h. The Defendants violated 21 CFR § 201.56 because the labeling was not informative and accurate.
- i. The prescription drug Actos is misbranded pursuant to 21 CFR § 201.56 because the labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading.
- j. The Defendants violated 21 CFR § 201.57 by failing to provide information that is important to the safe and effective use of the drug including the potential of Actos cause and the need for regular and/or consistent cardiac monitoring to ensure that a potential fatal cardiac arrhythmia has not developed.
- k. The Defendants violated 21 CFR § 201.57 because they failed to identify specific tests needed for selection or monitoring of patients who took the prescription drug Actos.
- l. The Defendants violated 21 CFR § 201.57 because the safety considerations regarding the prescription drug Actos are such that the drug should be reserved for certain situations, and the Defendants failed to state such information.
- m. The prescription drug Actos is mislabeled pursuant to 21 CFR § 201.57 because the labeling fails to describe serious adverse reactions and potential safety hazards, limitations in use imposed by it, and steps that should be taken if they occur.
- n. The prescription drug Actos is mislabeled pursuant to 21 CFR § 201.57 because the labeling was not revised to include a warning as soon as there was reasonable evidence of an association of a serious hazard with the drug.
- o. The Defendants violated 21 CFR § 201.57 because the labeling failed to list the adverse reactions that occur with the prescription drug Actos and other drugs in the same pharmacologically active and chemically related class.
- p. The Defendants violated 21 CFR § 201.57 because the possibility that a patient could develop Cardiac Arrhythmia after significantly more severe than the other reactions listed in the adverse reactions, and yet the Defendants failed to list the development of Cardiac Arrhythmia before the other adverse reactions on the labeling of the prescription drug Actos.

- q. The prescription drug Actos is mislabeled pursuant to 21 CFR § 201.57 because the labeling does not state the recommended usual dose, the usual dosage range, and, if appropriate, an upper limit beyond which safety and effectiveness have not been established.
- r. The prescription drug Actos violates 21 CFR § 210.1 because the process by which it was manufactured, processed, and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing, or holding of a drug to assure that it meets the requirements as to safety and have the identity and strength and meets the quality and purity characteristic that they purport or are represented to possess.
- s. The prescription drug Actos violates 21 CFR § 210.122 because the labeling and packaging materials do not meet the appropriate specifications.
- t. The prescription drug Actos violates 21 CFR § 211.165 because the test methods employed by the Defendants are not accurate, sensitive, specific, and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods have not been properly established and documented.
- u. The prescription drug Actos violates 21 CFR § 211.165 in that the prescription drug ACTOS fails to meet established standards or specifications and any other relevant quality control criteria.
- v. The prescription drug Actos violates 21 CFR § 211.198 because the written procedures describing the handling of all written and oral complaints regarding the prescription drug Actos were not followed.
- w. The prescription drug Actos violates 21 CFR § 310.303 in that the prescription drug Actos is not safe and effective for its intended use.
- x. The Defendants violated 21 CFR § 310.303 because the Defendants failed to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA.
- y. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to report adverse events associated with the prescription drug Actos as soon as possible or at least within 15 days of the initial receipt by the Defendants of the adverse drugs experience.
- z. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to conduct an investigation of each adverse event associated with the prescription drug Actos, and evaluating the cause of the adverse event.

- aa. The Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experiences and submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA.
- bb. The Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse drug experiences.
- cc. The Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to identify the reports they submitted properly, such as by labeling them as “15-day Alert report,” or “15-day Alert report followup.”
- dd. The Defendants violated 21 CFR § 312.32 because they failed to review all information relevant to the safety of the prescription drug Actos or otherwise received by the Defendants from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor.
- ee. The Defendants violated 21 CFR § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse drug experience not already reported under the Post marketing 15-day Alert report, and/or (c) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated).
- ff. The Defendants violated 21 CFR § 314.80 by failing to submit a copy of the published article from scientific or medical journals along with one or more 15-day Alert reports based on information from the scientific literature.

66. Defendants failed to meet the standard of care set by the above statutes and regulations, which were intended for the benefit of individual consumers such as the Plaintiff, making the Defendants liable under Ohio law.

**FIRST CAUSE OF ACTION**  
**PRODUCT DEFECT IN DESIGN OR FORMULATION**  
**OHIO REVISED CODE § 2307.75**

67. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if fully set forth herein.

68. At all times herein mentioned, Defendants manufactured, designed, formulated, produced, created, made, constructed and/or assembled Actos, used by Plaintiff.

69. Defendants' Actos was defective in that at the time Actos left the control of Defendants, the foreseeable risks associated with its design or formulation exceeded the benefits associated with that design or formulation.

70. The Defendants' Actos was in an unsafe, defective, and inherently dangerous condition which was unreasonably dangerous to its users and, in particular, Plaintiff.

71. At all times herein mentioned, Defendants' Actos was in a defective condition and unsafe, and Defendants knew, had reason to know, or should have known that said Actos was defective and unsafe, especially when used as instructed and in the form and manner as provided by Defendants.

72. The nature and magnitude of the risk of harm associated with the design and formulation of Defendants' Actos, including bladder cancer, is high in light of the intended and reasonably foreseeable use of Actos for type II diabetes.

73. It is highly unlikely that Actos users would be aware of the risks associated with Defendants' Actos through either warnings, general knowledge or otherwise. Plaintiff was not aware of said risks.

74. The likelihood was high that the design or formulation would cause the harm of bladder cancer, in light of the intended and reasonably foreseeable use of Actos to for type II diabetes.

75. The design or formulation did not conform to any applicable public or private product standard that was in effect when Actos left the control of its manufacturer, the Defendants.

76. The design or formulation of Defendants' Actos is more dangerous than a reasonably prudent consumer would expect when used in the intended or reasonable foreseeable manner for type II diabetes. It was more dangerous than Plaintiff expected.

77. The intended or actual utility of Defendants' Actos is not of such benefit to justify the risk of bladder cancer and even death.

78. There was both technical and economic feasibility, at the time the Defendants' Actos left Defendants' control, of using an alternative design or formulation that would not cause bladder cancer.

79. The defective design or formulation of Defendants' Actos was not caused by an inherent characteristic of Actos which is a generic aspect of antidiabetic medications, and which cannot be eliminated without substantially compromising Actos' usefulness or desirability and which is recognized by the ordinary person. This is demonstrated by numerous safer alternative therapies that are available on the market to treat type II diabetes, that effectively reduce blood sugar without the harmful side effects, such as bladder cancer, that can result from long-term Actos use.

80. A practical and technically feasible alternative design or formulation was available that would have prevented the harm for which Plaintiff suffered.

81. By reason of the foregoing, the Defendants are liable to the Plaintiff for the manufacturing, designing, formulating, producing, creating, making, constructing, and/or assembling a product that is defective in design and formulation.

**SECOND CAUSE OF ACTION**  
**PRODUCT DEFECT DUE TO INADEQUATE**  
**WARNING AND/OR INSTRUCTION**  
**OHIO REVISED CODE § 2307.76**

82. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if fully set forth herein.

83. Defendants had a duty to warn Plaintiff of the risks associated with the Defendants' Actos, namely, the risk of bladder cancer.

84. Defendants knew, or in the exercise or reasonable care, should have known about the risk of bladder cancer.

85. Defendants failed to provide warnings or instructions that a manufacturer exercising reasonable care would have provided concerning the risk of bladder cancer, in light of the likelihood that their product would cause bladder cancer, for which Plaintiff suffered.

86. Defendants' Actos is defective due to inadequate post-marketing warning or instruction.

87. Defendants knew, or in the exercise or reasonable care, should have known about the risk that their Actos causes bladder cancer.

88. Defendants failed to provide post-marketing warnings or instructions that a manufacturer exercising reasonable care would have provided concerning the risk of bladder cancer, in light of the likelihood that the product causes bladder cancer, for which Plaintiff suffered.

89. Defendants' product does not contain a warning or instruction regarding bladder cancer for normal healthy individuals.

90. The risk of bladder cancer is not an open and obvious risk or a risk that is a matter of common knowledge in regards to Actos.

91. By reason of the foregoing, the Defendants are liable to the Plaintiff, for the manufacturing, designing, formulating, producing, creating, making, constructing, and/or assembling a product that is defective due to inadequate warning or instruction.

**THIRD CAUSE OF ACTION**  
**PRODUCT DEFECT IN FAILURE TO CONFORM TO REPRESENTATIONS**  
**OHIO REVISED CODE § 2307.77**

92. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if fully set forth herein.

93. The Defendants' product was defective in that, when it left the control of Defendants, the product did not conform to representations made by Defendants.

94. Said representations are false, misleading, and inaccurate.

95. Defendants describe and represent that their product has characteristics that simply do not conform to reality. Rather than acknowledging that Defendants' product causes bladder cancer, Defendants describe Actos as being safe.

96. These representations are in stark contrast to the bladder cancer that Defendants' Actos does actually cause.

97. While Plaintiff believes and avers that Defendants acted negligently and recklessly in making the representations, in the event Defendants are not found to have acted

negligently or recklessly, Defendants are still liable for the damages and injuries suffered by Plaintiffs pursuant to ORC § 2307.77.

98. By reason of the foregoing, the Defendants are liable to the Plaintiff for the manufacturing, designing, formulating, producing, creating, making, constructing, and/or assembling a product that is defective in that it did not conform, at the time it left the control of Defendants, to representations made by Defendants.

**FOURTH CAUSE OF ACTION**  
**VIOLATION OF CONSUMER PROTECTION STATUTES**

99. Plaintiff repeats, reiterates, realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

100. Defendants engaged in commercial conduct by selling Actos.

101. Defendants misrepresented and omitted material information regarding Actos by failing to disclose known risks, including bladder cancer.

102. Defendants' misrepresentations and concealment of material facts constitute unconscionable commercial practices, deception, fraud, false pretenses, misrepresentation, and/or the knowing concealment, suppression, or omission of materials facts with the intent that others rely on such concealment, suppression, or omission in connection with the sale and advertisement of Defendants' product in violation of Sections 1345 and 4165 of the Ohio Revised Code.

103. Ohio has enacted statutes to protect consumers from deceptive, fraudulent, and unconscionable trade and business practices. Defendants violated these statutes by knowingly and falsely representing that Defendants' product was fit to be used for the purpose for which it was intended, when Defendants knew it was defective, dangerous, unsafe and by other acts alleged herein.

104. Defendants engaged in the deceptive acts and practices alleged herein in order to sell Defendants' product to the public, including Plaintiff.

105. As a direct and proximate result of the Defendants' violations of Chapters 1345 and 4165 of the Ohio Revised Code, Plaintiff suffered bladder cancer. Plaintiff is entitled to compensatory damages, equitable relief, punitive damages, costs and reasonable attorneys' fees.

### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff demands judgment against Defendants, as follows:

- a. Awarding actual damages to the Plaintiff incidental to his purchase and use of Actos in an amount to be determined at trial;
- b. Awarding treble and/or punitive damages to the Plaintiffs;
- c. Awarding pre-judgment and post-judgment interest to the Plaintiffs;
- d. Awarding the costs and the expenses of this litigation to the Plaintiffs;
- e. Awarding reasonable attorneys' fees and costs to the Plaintiffs as provided by law; and
- f. Granting all such other relief as the Court deems necessary, just and proper.

### **DEMAND FOR JURY TRIAL**

The Plaintiff hereby demands a trial by jury on all counts and as to all issues.

/s/ John R. Climaco

John R. Climaco (OH #0011456)

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